

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
TRUMBULL MEMORIAL HOSPITAL**

I. PREAMBLE

Trumbull Memorial Hospital ("Trumbull") hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance among its staff physicians and ensure compliance by its contract physicians, employees, and other contract health care professionals, as well as all third parties with whom Trumbull may choose to engage to act as billing or coding agents, with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))(hereinafter collectively referred to as the "Federal health care programs."). Through its own compliance efforts, Trumbull voluntarily self-disclosed to the Medicare program the billing issues giving rise to this CIA. Trumbull's compliance with the terms and conditions in this CIA shall constitute an element of Trumbull's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, Trumbull is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Trumbull under this CIA shall be three (3) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the date on which the final signatory of this CIA executes this CIA (the "effective date").

III. CORPORATE INTEGRITY OBLIGATIONS

Trumbull has entered into a previous settlement agreement with the United States dated June 1, 1998, and Trumbull has adopted certain compliance measures required by that agreement. The provisions of this CIA shall be in addition to and not in derogation of Trumbull's obligations under the terms of such June 1, 1998 settlement agreement. Trumbull represents that prior to the execution of this June 1, 1998 agreement, Trumbull formally commenced a compliance program (hereinafter referred to as the "Compliance Program"), which is aimed at ensuring that its participation in the Federal health care programs is in conformity with the statutes, regulations and other directives applicable to the programs. Therefore, pursuant to this CIA and for the duration of this CIA Trumbull hereby agrees to maintain in full operation its current Compliance Program, which as further represented by Trumbull, currently includes the following elements:

1. a Compliance Officer;
2. a Corporate Compliance Review Committee (hereinafter referred to as the "Compliance Committee") and multidisciplinary committees and subcommittees;
3. written Policies and Procedures including the following titled documents covering the indicated issues:
 - a. "Billing and Claims Submission Standards:" establishing policy covering Trumbull's legal obligation as a Federal health care program participant to submit accurate claims;
 - b. "Employee Discipline for Compliance Related Infractions:" establishing disciplinary policy for employees who violate compliance or legal standards;
 - c. "Employee Background Checks:" establishing policy for avoiding the hiring of individuals excluded from Federal Government programs;
 - d. "Employee Reporting Obligations:" establishing policy for reporting of violation or suspected violation of fraud and abuse laws and regulations;
 - e. "Employee Obligations:" establishing policy covering employee obligation to attend training, adhere to the Compliance Program, and report actual or possible violations of fraud and abuse laws and regulations;

- f. “‘Hot Line’ Reporting:” establishing a Hot Line for reporting of actual or potential compliance violations;
 - g. “Notice to Agents:” notifying contractors of Trumbull’s Compliance Program and commitment to the Program; and
 - h. “Third Party Audits:” establishing policy covering notification to Trumbull by its employees of any third-party reviews or audits;
- 4. a Training and Education Program (focused primarily on laboratory billing personnel and issues);
 - 5. a Hot Line (which shall constitute Trumbull’s Confidential Disclosure Program); and
 - 6. Audits and Monitoring of policies, procedures and practices pertinent to laboratory billing.

Trumbull hereby agrees to include within its current Compliance Program the following additional elements:

A. Policies and Procedures.

1. Written Standards: Trumbull shall incorporate into its existing Compliance Program written Policies and Procedures specifically demonstrating its commitment to the preparation and submission of accurate billings for self-administered drugs provided in an outpatient setting (hereinafter referred to as “self-administered drugs”) consistent with the standards in all federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs. Trumbull shall assess and update as necessary these Policies and Procedures regarding self-administered drugs as appropriate, but in any event at least annually. These new written Policies and Procedures will be available to OIG upon request.

Within ninety (90) days of the effective date of the CIA, these new written Policies and Procedures shall be distributed to all employees with responsibility for provision, documentation or billing for self-administered drugs and third parties with whom Trumbull may choose to engage to act as billing or coding agents. Compliance staff or supervisors should be available to explain these new Policies and Procedures.

2. *Operational Requirements:* Trumbull shall review its current Pharmacy billing system and where appropriate revise or create an adequate billing system that, to the fullest extent possible, properly and accurately bills for self-administered drugs and ensures that non-covered drugs are not billed to Federal health care programs in any manner, contrary to statute and regulations.

Prior to making any systematic changes to the process in which self-administered drugs are coded for billing to Medicare or any other Federal health care program (whether based on recommendations of third party contractors or employees), Trumbull shall review and adequately analyze the propriety of such changes. The review and analysis shall be conducted by a committee comprised of, at a minimum, the following individuals: the Compliance Officer or his or her designee, a Trumbull reimbursement representative, and a senior administrative officer or medical director from department(s) affected by the coding or billing change. In evaluating the proposed change, the aforementioned committee shall consider all applicable statutes, regulations, policies, procedures, program requirements and guidance from Medicare, Medicaid and all other Federal health care programs and their contractors.

B. Training and Education.

1. *Specific Training.* Within ninety (90) days of the effective date of this CIA, each employee who is involved directly or indirectly in the preparation or submission of claims for reimbursement for self-administered drugs (including, but not limited to, coding and billing) for any Federal health care programs shall receive at least one (1) hour of training regarding the proper billing of self-administered drugs. These training materials shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the subject area. Affected new employees shall receive this training within thirty (30) days of the beginning of their employment or within ninety (90) days of the effective date of this CIA, whichever is later. Each year, every affected employee shall receive such specific training.

2. *Certification.* Each affected employee shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with specific course materials. These shall be made available to OIG upon request.

C. Confidential Disclosure Program.

Trumbull shall amend its current "Hot Line" Reporting policy and procedure to indicate and ensure that all employee reports through the "Hot Line" shall be treated

confidentially. Further, the Confidential Disclosure Program shall require the Compliance Officer (or designee) to gather the information in such a way as to elicit all relevant information from the individual reporting the alleged misconduct. The Compliance Officer (or designee) shall make a preliminary good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides an opportunity for taking corrective action, Trumbull shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

D. Review Procedures.

Trumbull shall perform an internal audit to assess the adequacy of its billing system for self-administered drugs. This shall be an annual requirement and shall cover a twelve (12) month period. The internal audit shall be performed in accordance with the procedures described in Exhibit A (hereinafter referred to as “agreed-upon procedures”). Trumbull shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter “Independent Review Organization”), to review whether Trumbull has performed the internal audit in conformance with the agreed-upon procedures as described in Exhibit A. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which Trumbull seeks reimbursement. Trumbull shall require the Independent Review Organization to produce a report on its findings, which report shall be included in Trumbull’s Annual Report to the OIG.

E. Notification of Proceedings.

Within thirty (30) days of discovery, Trumbull shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Trumbull has committed a crime or has engaged in fraudulent activities or any other knowing misconduct. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Trumbull shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

F. Reporting.

1. *Credible evidence of misconduct.* If Trumbull discovers credible evidence of misconduct from any source and, after reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil, or administrative law concerning Trumbull's practices relating to the Federal health care programs, then Trumbull shall promptly report the probable violation of law to OIG. Trumbull shall make this disclosure as soon as practicable, but not later than thirty (30) days after becoming aware of the existence of the probable violation. Trumbull's report to OIG shall include:

- a. the findings concerning the probable violation, including the nature and extent of the probable violation;
- b. Trumbull's actions to correct such probable violation; and
- c. any further steps it plans to take to address such probable violation and prevent it from recurring.

To the extent the misconduct involves an overpayment, the report shall include the information listed in Exhibit A regarding material deficiencies.

2. *Inappropriate Billing.* If, during the term of this CIA, Trumbull discovers inappropriate or incorrect Federal health care program overpayments for self-administered drugs to Trumbull through means other than its annual audit of the adequacy of its billing system regarding self-administered drugs, then Trumbull shall follow procedures in Exhibit A regarding overpayments and material deficiencies.

IV. ANNUAL REPORTS

A. Annual Report. Trumbull shall submit to OIG Annual Reports with respect to the status and findings of Trumbull's compliance activities. The Annual Reports shall include:

1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee which currently exists as part of Trumbull's Compliance Program;

2. a copy of the new Policies and Procedures required by section III.A and notification of any changes or amendments to the Policies and Procedures since the most recent prior report and the reasons for such changes;
3. a certification by the Compliance Officer that all affected employees have completed the training and executed the certification required by section III.B.
4. a complete copy of the internal audit report and the report of findings by the Independent Review Organization as required by section III.D;
5. Trumbull's response/corrective action plan to any issues raised as part of its internal audit of the adequacy of Trumbull's billing system regarding self-administered drugs;
6. a summary of material deficiencies reported throughout the course of the previous twelve (12) months pursuant to Exhibit A;
7. a report of the aggregate overpayments relating to self-administered drugs that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this CIA;
8. A description of the confidential disclosure program as required to be amended by section III.C. and a copy of the entries in the confidential disclosure log pertaining to billing for self-administered drugs as required by section III.C.
9. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Trumbull has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to section III.E. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;
10. a corrective action plan to address the probable violations of law identified in section III.F; and

11. a description of any personnel action (other than hiring) taken by Trumbull during the preceding year as a result of its current Compliance Program "Employee Background Checks" policy and procedure.

The first Annual Report shall be received by the OIG no later than one year and sixty (60) days after the effective date of this CIA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

B. Certifications. The Annual Report shall include a certification by the Compliance Officer under penalty of perjury, that: (1) Trumbull is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

V. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

Trumbull:

Karl Kuppler
Corporate Compliance Officer
Trumbull Memorial Hospital
1350 East Market Street
Warren, Ohio 44483-6628
Phone (330) 841-9011
Fax (330) 841-9121

VI. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s), may examine Trumbull's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) Trumbull's compliance with the terms of this CIA; and (b) Trumbull's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Trumbull to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Trumbull's employees who consent to be interviewed at the

employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee and OIG. For purposes of monitoring compliance with this CIA, OIG will contact the Trumbull Compliance Officer in advance for any requests to examine books, records, and other documents and supporting materials or interview witnesses under this section. Trumbull agrees to assist OIG in contacting and arranging interviews with such employees upon OIG's request. Trumbull's employees may elect to be interviewed with or without a representative of Trumbull present.

VII. DOCUMENT AND RECORD RETENTION

Trumbull shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, one year longer than the term of this CIA (or longer if otherwise required by law).

VIII. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Trumbull prior to any release by OIG of information submitted by Trumbull pursuant to its obligations under this CIA and identified upon submission by Trumbull as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Trumbull shall refrain from identifying any information as trade secrets, commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

IX. BREACH AND DEFAULT PROVISIONS

Trumbull is expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Trumbull and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning on the ninety-first day

following the effective date of this CIA and concluding at the end of the term of this CIA, Trumbull fails to have in place any of the following elements of its Compliance Program:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. written Policies and Procedures;
- d. a Training and Education Program; and
- e. a Confidential Disclosure Program.

2. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Trumbull fails to meet any of the deadlines to submit the Annual Reports to the OIG.

3. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the date the Trumbull fails to grant access) for each day Trumbull fails to grant access to the information or documentation as required in section VI of this CIA.

4. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date that OIG provides written notice to Trumbull of the failure to comply) for each day Trumbull fails to comply fully and adequately with any obligation of this CIA, except that such penalty shall not apply in combination with any of the Stipulated Penalties described above. In its written notice to Trumbull, the OIG shall state the specific grounds for its determination that Trumbull has failed to comply fully and adequately with the CIA obligation(s) at issue.

B. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Trumbull has failed to comply with any of the obligations described in section IX.A and determining that Stipulated Penalties are appropriate, OIG shall notify Trumbull by personal service or certified mail of (a) Trumbull's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within fifteen (15) days of the date of the Demand Letter, Trumbull shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section IX.D. In the event Trumbull elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Trumbull cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section IX.C.

2. *Timely Written Requests for Extensions.* Trumbull may submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Trumbull fails to meet the revised deadline as agreed to by the OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after Trumbull receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section V.

4. *Independence from Material Breach Determination.* Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that Trumbull has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section IX.C, below.

C. Monetary Penalty for Material Breach of this CIA.

1. *Material Breach Defined.* A material breach of this CIA means:

- (i) a failure by Trumbull to report a known material deficiency, take corrective action and pay the appropriate refunds, as provided in Exhibit A;
- (ii) repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section IX.A; or
- (iii) a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section IX.B above.

2. *Notice of Material Breach and Intent to Collect Material Breach Penalty.*

The parties agree that a material breach of this CIA by Trumbull constitutes grounds for the OIG to impose an enhanced stipulated penalty that is separate and apart from the Stipulated Penalties described in section IX.A-B. This monetary penalty (hereinafter referred to as the "Material Breach Penalty") shall be \$15,000 per day. Upon a determination by the OIG that Trumbull has materially breached this CIA and that a Material Breach Penalty should be imposed, the OIG shall notify Trumbull by certified mail of: (i) Trumbull's material breach; and (ii) the OIG's intent to exercise its contractual right to impose the Material Breach Penalty (this notification is hereinafter referred to as the "Notice of Material Breach Letter"). In its Notice of Material Breach Letter, the OIG shall state the specific grounds for its determination that Trumbull has materially breached this CIA.

3. *Opportunity to Cure.* Trumbull shall have thirty-five (35) days from the date of receipt of the Notice of Material Breach Letter to demonstrate to the OIG's reasonable satisfaction that:

- (a) Trumbull is in full compliance with this CIA;
- (b) the alleged material breach has been cured; or
- (c) the alleged material breach cannot be cured within the thirty-five (35) day period, but that (i) Trumbull has begun to take action to cure the material breach; (ii) Trumbull is pursuing

such action with due diligence; and (iii) Trumbull has provided to the OIG a reasonable timetable for curing the material breach.

4. *Penalty Letter.* If, at the conclusion of the thirty-five (35) day period, Trumbull fails to satisfy the requirements of section IX.C.3, the OIG may impose the Material Breach Penalty on Trumbull and the penalty will begin to accrue on that day. The OIG will notify Trumbull in writing of its determination to impose the Material Breach Penalty (this letter shall be referred to hereinafter as the "Material Breach Penalty Letter"). Within fifteen (15) days of receipt of the Material Breach Penalty Letter, Trumbull shall either: (i) cure the material breach to the OIG's satisfaction and pay the applicable Material Breach Penalty; or (ii) request a hearing before an HHS administrative law judge (ALJ) to dispute the OIG's determination of material breach, pursuant to the agreed upon provisions set forth below in section IX.D. In the event Trumbull elects to request an ALJ hearing, the Material Breach Penalties shall continue to accrue until Trumbull cures, to the OIG's satisfaction, the alleged material breach in dispute.

D. Dispute Resolution.

1. *Review Rights.* Upon the OIG's delivery to Trumbull of its Demand Letter or of its Material Breach Penalty Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Trumbull shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005 as if they applied to the Stipulated Penalties or Material Breach Penalties sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or Material Breach Penalties shall be subject to review by an ALJ and/or the Departmental Appeals Board (DAB) in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties or Material Breach Penalties shall be made within fifteen (15) days of the date of receipt of the Demand Letter or the Penalty Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (i) whether Trumbull was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and, (ii) the period of noncompliance. Trumbull shall have the burden of proving its full and timely compliance and the steps taken to cure the

noncompliance, if any. If the ALJ finds for the OIG with regard to whether there was a breach of this CIA and orders Trumbull to pay Stipulated Penalties, such Stipulated Penalties shall be due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Trumbull may request review of the ALJ decision by the DAB.

3. *Material Breach Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding regarding imposition of the Material Breach Penalty shall be: (a) whether Trumbull was in material breach of this CIA; (b) whether Trumbull had cured the Material Breach by the date of the Material Breach Penalty Letter; or (c) whether the alleged material breach could not be cured within the thirty-five (35) day period, but that (i) Trumbull began to take action to cure the material breach; (ii) Trumbull pursued such action with due diligence; and (iii) Trumbull provided to the OIG a reasonable timetable for curing the material breach.

If Trumbull invokes the Dispute Resolution Procedures in this section, the Material Breach Penalty shall be imposed only after an ALJ decision which is favorable to the OIG. The applicable Material Breach Penalty will be based on the number of days between the date of the Material Breach Penalty Letter and the date of the ALB decision favorable to the OIG. Trumbull's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to impose the Material Breach Penalty upon Trumbull upon the issuance of the ALJ's decision. If the ALJ sustains the OIG's decision and determines that the imposition of such penalty is authorized, payment of the Material Breach Penalty will be required twenty (20) days after the ALJ issues such a decision notwithstanding that Trumbull may request review of the ALJ decision by the DAB.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and Trumbull agrees to waive any right it may have to appeal the decision administratively, judicially or otherwise seek review by any court or other adjudicative forum.

X. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Trumbull and OIG agree as follows:

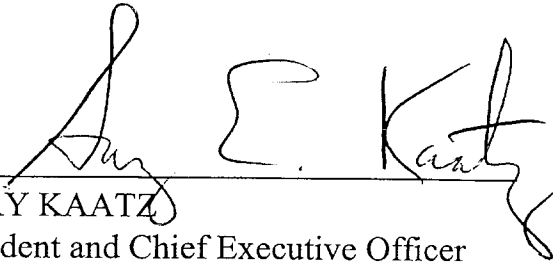
A. This CIA shall be binding on the successors, assigns and transferees of Trumbull;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and

D. The undersigned Trumbull signatory represents and warrant that he/she is authorized to execute this CIA. The undersigned OIG signatory represents that he/she is signing this CIA in his/her official capacity and that he/she is authorized to execute this CIA.


ON BEHALF OF TRUMBULL MEMORIAL HOSPITAL



GARY KAATZ
President and Chief Executive Officer
Trumbull Memorial Hospital

5/7/99
DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

5/25/99
DATE

Exhibit A

1. *Internal Audit.* The internal audit required by section III.D (“Billing Audit”), shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims submitted to the Federal health care programs for the relevant period. The sample size shall be determined through the use of a probe sample. At a minimum, the full sample must be within a ninety (90) percent confidence level and a precision of twenty-five (25) percent. The probe sample must contain at least thirty (30) sample units and cannot be used as part of the full sample. Both the probe sample and the sample must be selected through random numbers. Trumbull shall use OIG’s Office of Audit Services Statistical Sampling Software, also known as “RAT-STATS,” which is available through the Internet at “www.hhs.gov/progorg/oas/ratstat.html”.

Each annual Billing Audit shall include the following components in its methodology:

- a. **Billing Audit Objective:** A statement stating clearly the objective intended to be achieved by the Billing Audit and the procedure or combination of procedures that will be applied to achieve the objective.
- b. **Billing Audit Population:** Identify the population, which is the group about which information is needed. Explain the methodology used to develop the population and provide the basis for this determination.
- c. **Sources of Data:** Provide a full description of the source of the information upon which the Billing Audit conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations.
- d. **Sampling Unit:** Define the sampling unit, which is any of the designated elements that comprise the population of interest.
- e. **Sampling Frame:** Identify the sampling frame, which is the totality of the sampling units from which the sample will be selected.

The Billing Audit shall provide:

- a. findings regarding Trumbull’s billing and coding operation for

self-administered drugs (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, effectiveness of the system);

b. findings regarding whether Trumbull is submitting accurate claims and/or cost reports with respect to self-administered drugs for services billed to the Federal health care programs;

c. findings regarding Trumbull's procedures to correct inaccurate billings or codings for self-administered drugs to the Federal health care programs; and

d. findings regarding the steps Trumbull is taking to bring its operations into compliance or to correct problems identified by the audit.

A complete copy of Trumbull's Billing Audit report and the report of findings by the Independent Review Organization shall be included in each of Trumbull's Annual Reports to OIG.

2. *Disclosure of Overpayments and Material Deficiencies.* If, as a result of the Billing Audit, Trumbull identifies any billing, coding or other policies, procedures and/or practices that result in an overpayment to Trumbull from any Federal health care program, Trumbull shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering the deficiency or overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the deficiency from recurring. The notice to the payor shall include:

a. a statement that the refund is being made pursuant to this CIA;

b. a description of the complete circumstances surrounding the overpayment;

c. the methodology by which the overpayment was determined;

d. the amount of the overpayment;

- e. any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date);
- f. the cost reporting period; and
- g. the provider identification number under which the repayment is being made.

If Trumbull determines an overpayment represents a material deficiency, contemporaneous with Trumbull's notification to the payor as provided above, Trumbull shall also notify OIG of:

- a. a complete description of the material deficiency;
- b. amount of overpayment due to the material deficiency;
- c. Trumbull's action(s) to correct and prevent such material deficiency from recurring;
- d. the payor's name, address, and contact person where the overpayment was sent; and
- e. the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid.

For purposes of this CIA, an "overpayment" shall mean the amount of money Trumbull has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or program directives, including carrier and intermediary instructions.

For purposes of this CIA, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to the Federal health care programs; (ii) conduct or policies that clearly violate the Federal health care program statutes, regulations or directives issued by HCFA or other Federal health care program regulators and/or their agents issuing payment to Trumbull; or (iii) serious quality of care implications for federal health care beneficiaries or recipients. A material deficiency may be the result of an isolated event or a series of occurrences.

3. *Verification/Validation.* In the event that the OIG has reason to believe that Trumbull's Billing Audit fails to conform to its obligations under the CIA or indicates improper billings not otherwise adequately addressed in the audit report, and thus determines that it is necessary to conduct an independent review to determine whether or the extent to which Trumbull is complying with its obligations under this CIA, Trumbull agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.